IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SCIELE PHARMA, INC., ANDRX CORPORATION, ANDRX PHARMACEUTICALS, INC. (N/K/A WATSON LABORATORIES, INC.-FLORIDA), ANDRX PHARMACEUTICALS, L.L.C., ANDRX LABORATORIES (NJ), INC., ANDRX EU LTD., AND ANDRX LABS, L.L.C., Plaintiffs, v. LUPIN LTD., and LUPIN PHARMACEUTICALS, INC., Defendants.	C.A. No. 09-037 (RBK)(JS) CONSOLIDATED REDACTED - PUBLIC VERSION
SHIONOGI, INC., ANDRX CORPORATION, ANDRX PHARMACEUTICALS, INC. (N/K/A WATSON LABORATORIES, INC.-FLORIDA), ANDRX PHARMACEUTICALS, L.L.C., ANDRX LABORATORIES (NJ), INC., ANDRX EU LTD., AND ANDRX LABS, L.L.C., Plaintiffs, v. MYLAN, INC., and MYLAN PHARMACEUTICALS INC., Defendants.	C.A. No. 10-135 (RBK)(JS)

PLAINTIFF SHIONOGI INC.'S OPENING BRIEF IN SUPPORT OF
MOTION FOR PRELIMINARY INJUNCTION AND RECALL

MORRIS, NICHOLS, ARSHT & TUNNELL LLP
Jack B. Blumenfeld (#1014)
Karen Jacobs Louden (#2881)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@mnat.com
klouden@mnat.com

Attorneys for Plaintiff Shionogi

OF COUNSEL:

Christopher R. Noyes
WILMER CUTLER PICKERING HALE AND DORR LLP
60 State Street
Boston, MA 02109
(617) 626-6000

David A. Manspeizer
David B. Bassett
Peter Shen
WILMER CUTLER PICKERING HALE AND DORR LLP
399 Park Avenue
New York, NY 10022
(212) 230-8800

Liza M. Walsh
Rukhsanah Lighari
CONNELL FOLEY LLP
85 Livingston Avenue
Roseland, NJ 07068
(201) 521-1000

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I. NATURE AND STAGE OF PROCEEDINGS

Plaintiffs Sciele Pharma, Inc., n/k/a Shionogi Inc. ("Shionogi") move for an order preliminarily enjoining defendants Lupin, Ltd., an Indian company, and its U.S. subsidiary Lupin Pharmaceuticals, Inc. ("Lupin"), from further importation and sales of its generic copy of Shionogi's Type 2 diabetes drug, FORTAMET®, and for a recall of generic product already in the market.[1]

Without waiting for this Court to make its determination on the merits, Lupin decided to take matters into its own hands and **REDACTED** of its generic copy of FORTAMET on September 30, 2011. (Declaration of Christopher Noyes ("Noyes Decl."), Ex. 12.) Lupin's generic product infringes the two valid, unexpired patents at issue in this lawsuit, U.S. Patent Nos. 6,099,859 ("the '859 Patent") and 6,866,866 ("the '866 Patent").[2] If Lupin is allowed to keep its generic product on the market and to sell the large quantities it has already made, and continues to make, the U.S. market for FORTAMET will be flooded with generic drugs from India that infringe Plaintiffs' intellectual property rights, destroying the market for branded FORTAMET in the United States. The resulting harm to Shionogi, which holds the exclusive right to sell FORTAMET in the United States, will be extensive and irreparable. Immediate and emergency relief from the Court—including an order directing Lupin to recall its generic products—is necessary to protect Shionogi from additional harm and

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1 Plaintiffs Andrx Corporation; Andrx Pharmaceuticals, Inc., n/k/a Watson Laboratories, Inc. – Florida; Andrx Pharmaceuticals L.L.C.; Andrx Laboratories (NJ), Inc.; Andrx EU Ltd.; and Andrx Labs, L.L.C. (collectively "Andrx") do not oppose this motion or its requested relief.

2 Plaintiffs Shionogi and Andrx have accused Lupin of infringing claim 3 of the '859 patent, and claims 1, 3-5, and 25 of the '866 patent. To simplify the issues for the Court on this motion for preliminary injunction, Plaintiffs will focus this motion only on the asserted claims of the '866 patent. (*See* Noyes Decl., Ex. 1, Plaintiffs' Disclosure of Asserted Claims and Infringement Contentions). However, Plaintiffs reserve all rights to assert the '859 patent against Lupin in this litigation, including on summary judgment and at trial.

to preserve the now fragile market for FORTAMET created by Lupin's "at-risk launch."[3]

II. SUMMARY OF ARGUMENT

The need to restrain Lupin from importing, offering to sell and selling an infringing generic copy of FORTAMET is compelling, and each element for a preliminary injunction is satisfied:

First, Plaintiffs are likely to prevail on the merits of their infringement claim because Lupin's generic copy of FORTAMET meets each limitation of at least claims 1, 3-5 and 25 of the '866 patent. **REDACTED**

REDACTED

REDACTED (Noyes Decl. Ex. 2, (Lupin's approved label (emphasis added)). That label, which under federal law must be truthful and accurate, is compelling evidence of infringement. The Court need look no further to determine Plaintiffs' likelihood of success on the infringement issue.

In addition, Lupin cannot meet its heavy burden showing that claims 1, 3-5 and 25 of the '866 patent are invalid. The '866 patent is entitled to a presumption of validity. Therefore, Plaintiffs need not prove that the '866 patent is valid. Rather, Lupin must prove invalidity at trial by clear and convincing evidence, and on this motion, Lupin must establish a likelihood of proving invalidity by clear and convincing evidence. Lupin faces an almost insurmountable challenge here because it relies almost exclusively on prior art already considered by the Patent

[3] The term "at-risk launch" is used in situations such as this, where a generic drug manufacturer launches its product into the market place before a final determination on the merits, because the generic manufacturer is "at risk" of incurring substantial damages for infringement.

Office. "When the party asserting invalidity relies on references that were considered during examination or reexamination, that party bears the added burden of overcoming the deference that is due to a qualified government agency presumed to have done its job." *PharmStem Therapeutics v. Viacell, Inc.*, 491 F.3d 1342, 1366 (Fed. Cir. 2007) (internal quotations omitted). Lupin does not, and cannot, meet this heavy burden.

Second, the harm Shionogi has suffered and will continue to suffer as a result of Lupin's decision to launch its generic copy of FORTAMET is not readily quantifiable and is irreparable in monetary terms. Here, Plaintiffs' likelihood of success on the merits of their infringement claim is strong evidence of irreparable harm. But even apart from that evidence, irreparable harm is firmly established by the immediate, adverse impact upon FORTAMET sales that will result from Lupin saturating the market with its infringing generic copy and **REDACTED**

REDACTED

REDACTED That is the definition of irreparable harm.

Third, the balance of hardships overwhelmingly favors granting a preliminary injunction and ordering a recall of Lupin's generic copy of FORTAMET. In contrast to the immediate, substantial and irreversible harm to Shionogi, there would be no cognizable harm to Lupin in granting this motion. Lupin has a legal obligation not to infringe the '866 patent and thus has no basis to complain about an Order preventing it from doing so. Any alleged "harm" Lupin may suffer is of its own making.

Fourth, the relief requested is in the public interest, whose interest in honoring patent rights and encouraging innovation in the development of newer, safer and more effective drugs is well established. Those interests also favor Shionogi's requested relief, as it would permit Shionogi to continue to fund its development efforts for new therapies designed to address unmet medical needs, efforts threatened by Lupin's actions.

For these reasons, as more fully developed below, this Court should grant Shionogi's motion seeking a preliminary injunction and order a recall of Lupin's generic copy of FORTAMET.

III. STATEMENT OF FACTS

A. Shionogi Inc.

Shionogi is a U.S.-based wholly-owned subsidiary of Shionogi & Co. Ltd., a Japanese pharmaceutical company ("Shionogi Japan"). Shionogi develops and commercializes pharmaceutical products that address unmet medical needs. Currently, Shionogi is developing products to treat patients with a variety of diseases and conditions, **REDACTED** **REDACTED** (Declaration of Deanne Melloy ("Melloy Decl.") at ¶¶4-5.)

Today, Shionogi sells a portfolio of about twenty FDA-approved products, including FORTAMET. Shionogi actively promotes **REDACTED** in the United States. (Melloy Decl. at ¶5.) Shionogi also conducts market research and development in the United States for products in the development pipeline, **REDACTED** (*Id.*) In support of these sales and development efforts, Shionogi currently employs 569 people in the United States, including 169 people at its Florham Park, New Jersey headquarters. The company also has 35 employees in Georgia and 315 sales professionals in locations throughout the United States. (*Id.* at ¶6.)

B. FORTAMET and the Treatment of Type 2 Diabetes

One of Shionogi's most successful products is FORTAMET. The active ingredient of FORTAMET is a drug called metformin, an oral antihyperglycemic drug used in the management of type 2 diabetes. Diabetes is a metabolic disorder characterized by high blood glucose levels that result from defects in a patient's ability to produce and/or use insulin. (Declaration of Christopher Vellturo, PhD ("Vellturo Decl.") ¶ 8.) An estimated 25.8 million people, or 8.3 percent of the U.S. population, are affected by diabetes. (*Id.* at ¶9.) Type 2 diabetes is the most common form of diabetes, and occurs when a patient does not produce enough insulin or resists the effects of the insulin made by the body. (*Id.* at ¶8.) When this occurs, a patient cannot convert food into energy and, as a result, high levels of sugar remain in the patient's bloodstream. Over time, constant high blood sugar levels can cause damage to the eyes, heart, kidneys, and nerves. (*Id.*)

FORTAMET was approved by the FDA on April 28, 2004, and is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. (Melloy Decl. at ¶7.) FORTAMET extended release tablets use the patented controlled-release technology of the patents in suit, and enable once-a-day oral administration of the drug to patients. FORTAMET provides a consistent rate of drug delivery when patients need it most, *i.e.*, when their bodies are producing the highest levels of glucose. (Melloy Decl. at ¶10.) FORTAMET is available in two dosage forms, a 1,000 mg tablet and a 500 mg tablet. (*Id.* at ¶8.) The 500 mg tablet is prescribed primarily for titration, which refers to the process by which a patient is initially acclimated to a drug. (*Id.*) The 1,000 mg tablet is primarily used for maintenance dosing and **REDACTED**

REDACTED The maximum recommended daily dose of FORTAMET is 2,500 mg. (*Id.*, Exhibit A at 18, FDA approved label for FORTAMET).

FORTAMET is part of a class of drugs know as biguanides, which also includes the

branded drugs Glumetza® and Glucophage®, as well as generic metformin, REDACTED REDACTED (Melloy Decl. at ¶11.) Biguanides are one of the most trusted, safest and widely prescribed oral anti-diabetic agents on the market and are known as the "Gold Standard" for the treatment of type 2 diabetes. (Vellturo Decl. at ¶11.) Biguanides are primarily prescribed as first line therapy (before insulin) and continue to dominate the oral diabetes marketplace in total prescriptions. (*Id.*)

C. Sales and Promotion of FORTAMET

Despite competition from generic metformin and other branded biguanides, FORTAMET is a commercial success for Shionogi and a clinical success for doctors and patients. Since its introduction in 2004, FORTAMET has developed REDACTED physicians in the United States who regularly prescribe the drug to their patients. (Melloy Decl. at ¶10.) In 2010, FORTAMET had nearly REDACTED in gross sales, and REDACTED in profits. (Melloy Decl. at ¶14.). These sales accounted for approximately REDACTED percent of Shionogi's total net sales and a REDACTED of its operating profits in 2010. (*Id.*)

Although Shionogi stopped actively promoting FORTAMET to patients and physicians REDACTED it continues to be a successful and important product for the company. (Melloy Decl. at ¶¶12-14.). REDACTED REDACTED (*Id.* at ¶13.) REDACTED REDACTED (*Id.* at ¶14.) REDACTED

REDACTED

REDACTED (*Id.* at ¶¶13-17.).

D. The Patented Technology

Fundamental to the clinical and commercial success of FORTAMET is the novel

extended-release technology, which it embodies. (*See, e.g.*, Melloy Decl. at ¶10.) That technology is protected by numerous patents, including the '866 patent. (*See* Noyes Decl., Ex. 3 (FDA Orange Book listed patents covering 1000 mg FORTAMET); Vellturo Decl. at ¶14.) The '866 patent covers, *inter alia*, highly effective metformin-based formulations and dosing regimens that safely and effectively control and lower the amount of glucose (blood sugar) in adults suffering from type 2 diabetes.

Plaintiff Andrx owns the patents covering FORTAMET and holds the FDA-approved New Drug Application for the drug. Andrx granted Shionogi an exclusive license under the '866 and other patents to market, distribute, sell, and offer to sell FORTAMET in the United States. (Melloy Decl. at ¶9.) **REDACTED**

REDACTED

1. The '866 Patent

The '866 patent issued on March 15, 2005 and does not expire for nearly 10 years—on March 17, 2021. The patent discloses the invention of controlled release dosage forms that favorably result in peak blood plasma levels of metformin (T_{max}) between about 5.5 and 7.5 hours after a single dose is taken once a day, following dinner. (Noyes Decl. Ex. 4, '866 patent at 3:28-31). This single dose, once-a-day administration provides the highest blood plasma levels of drug at the time when the patient needs it most, *i.e.*, around 2 a.m., when the body is producing the most glucose. (*Id.* at 5:29-32).

The discovery disclosed and claimed in the '866 patent was a significant advance over past metformin treatments for hyperglycemia, which required twice-daily or three times daily dosing because of the short-acting nature of metformin. (*Id.* at 2:3-6.) The novel dosage forms of the '866 patent not only reduce the number of required doses a patient must take, but also the potentially dangerous side-effects of multiple daily doses, such as anorexia, nausea and

vomiting. (*See id.* at 2:5-16). Taken together, the new and nonobvious aspects of the '866 patent achieved the inventors' goal of "improv[ing] the quality of therapy in patients with [Type 2 diabetes] and the safety profile relative to a conventional dosage form." (*Id.* at 2:6-16.)

E. Lupin's ANDA Filing

In December 2008, Plaintiffs learned that Lupin had filed Abbreviated New Drug Application ("ANDA") No. 90-692 ("the Lupin ANDA") with the FDA seeking approval to manufacture and market a generic copy of FORTAMET before expiration of the '866 and '859 patents. (*See* Noyes Decl., Ex 5; D.I. 1, ¶ 20.) When an ANDA applicant seeks approval to sell a generic version of a patented drug listed in the FDA's Orange Book, the applicant must certify to the FDA the basis on which it seeks approval despite the existence of a patent covering the drug. The applicant must certify to the FDA that, to the best of the applicant's knowledge, one of the following applies: (1) no patent information has been submitted by the patentee to the FDA (a "Paragraph I certification"); (2) the patent has expired (a "Paragraph II certification"); (3) the applicant will not sell the generic drug until after the patent covering the drug has expired (a "Paragraph III certification"); or (4) the patent is invalid and/or will not be infringed by the generic drug (a "Paragraph IV certification"). 21 U.S.C. § 355(j)(2)(A)(vii); *see also* 21 C.F.R. § 314.94(a)(12).

F. Lupin's Paragraph IV Notification and Resulting Thirty-Month Stay

On December 3, 2008, Lupin sent a Paragraph IV certification to Andrx representing that it had filed its ANDA for a generic copy of FORTAMET, and certifying that, in Lupin's opinion,

REDACTED (D.I. 1, ¶ 21; Noyes Decl. Ex. 5 at ¶6.) Pursuant to procedures set forth in Hatch-Waxman Act[4], on January 15, 2009,

[4] Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585.

Plaintiffs filed suit against Lupin in the District of Delaware, alleging infringement of the '859 and '866 patents. (D.I. 1 at 1).[5] As a result, the FDA approval of Lupin's ANDA was stayed for thirty months pursuant to 21 U.S.C. § 355(j)(5)(B)(iii). In June 2011, the thirty-month stay on approval of Lupin's ANDA expired. On June 29, 2011, FDA approved Lupin's ANDA. (*See* Noyes Decl., Ex. 6.)

REDACTED

F. Lupin's At-Risk Launch Infringing Plaintiffs' Patents

Then, on the afternoon of Friday, September 30—the same day Lupin terminated the parties' settlement agreement—Plaintiffs began to hear rumors that, despite this pending litigation, Lupin either had launched or was making preparations to launch its generic copy of FORTAMET. Given the urgency of the situation, on Sunday, October 2, 2011, counsel for Shionogi asked Lupin's outside counsel to confirm "before noon on Monday, October 3rd, if Lupin is making preparation to launch and/or intends to launch its proposed generic product." (Noyes Decl., Ex. 8.) On the morning of October 3, Lupin's counsel informed Plaintiffs that "Lupin *launched* its product on Friday, September 30." (*Id.* (emphasis added).)

[5] In January 2010, Mylan notified Plaintiffs that it had also filed an ANDA for a generic copy of FORTAMET®. Plaintiffs likewise thereafter filed suit against Mylan in the District of Delaware, alleging infringement of the '859 and '866 patents. C.A No. 10-135, D.I. 1. Approval of Mylan's ANDA is currently stayed until June 2012.

IV. ARGUMENT

In the absence of injunctive relief, including recall of Lupin's generic product already in the market, Shionogi will continue to suffer immediate and irreparable harm as a direct result of Lupin's infringement of the '866 patent. The Court should, pursuant to 35 U.S.C. § 283, grant a preliminary injunction prohibiting Lupin from engaging in infringing activity in the United States, including the importation, manufacture, sale, or offer for sale of its generic copy of FORTAMET until the Court decides the issues of patent validity and infringement. In addition, the Court should order an immediate recall of the generic product Lupin has already put on the market. Courts have ordered recalls of generic pharmaceutical products in similar situations. *See, e.g., Ortho McNeil Pharm., Inc. v. Barr Labs., Inc.,* Civ. A. No. 03-4678 (SRC), 2009 WL 2182665 (D.N.J. July 22, 2009) (court ordered recall of Barr TCL products placed into stream of commerce).

A. The Standard for Preliminary Injunctive Relief

A party is entitled to a preliminary injunction if it establishes that: (1) it is likely to succeed on the merits; (2) it is likely to suffer irreparable harm in the absence of preliminary relief; (3) the balance of equities tips in its favor; and (4) an injunction is in the public interest. *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1049 (Fed. Cir. 2010). No one factor is dispositive and "[t]he court must balance these four factors, as their relative weights warrant, in service to the interest of justice." *Monsanto Co. v. McFarling*, 302 F.3d 1291, 1297 (Fed. Cir. 2002).

Although establishment of a reasonable likelihood of success on the merits (by making a clear showing of infringement and validity) cannot alone justify an injunction, it weighs strongly in favor of finding irreparable harm. *See Bosch v. Pylon Mfg. Corp.*, No. 2011-1096, slip. op. at 10-11 (Fed. Cir. October 12, 2011) (holding that a patentee's right to exclude "should not be

ignored" in evaluating injunctive relief); *Acumed LLC v. Stryker Corp.*, 551 F.3d 1323, 1328 (Fed. Cir. 2008) (finding in a post-*eBay* decision that, "[i]n view of that right [to exclude], infringement may cause a patentee irreparable harm not remediable by a reasonable royalty"). Indeed, just today the Federal Circuit made clear that:

> [a]lthough eBay abolishes our general rule that an injunction normally will issue when a patent is found to have been valid and infringed, it does not swing the pendulum in the opposite direction. In other words, even though a successful patent infringement plaintiff can no longer rely on presumptions or other short-cuts to support a request for [an] injunction, it does not follow that courts should entirely ignore the fundamental nature of patents as property rights granting the owner the right to exclude.

Bosch, slip op. at 10-11.

B. Injunctive Relief Is Appropriate in This Case

1. Plaintiffs Are Likely to Succeed on the Merits of Its Claims

To establish their entitlement to a preliminary injunction, Plaintiffs need to demonstrate, consistent with the underlying burdens of proof at trial, that they will likely prove infringement and that the '866 patent will likely withstand Lupin's challenge to its validity. *Sanofi-Synthelabo*, 470 F.3d at 1374; *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1363 (Fed. Cir. 2001).

For infringement, Plaintiffs must prove at trial, by a preponderance of the evidence, that Lupin's generic copy of FORTAMET infringes the '866 patent. *Kegel Company, Inc. v. AMF Bowling, Inc.*, 127 F.3d 1420, 1425 (Fed. Cir. 1997).

With respect to validity, a patent is presumed valid, and the burden of overcoming that presumption rests on the party challenging the patent's validity. 35 U.S.C. § 282. Thus, at trial, the alleged infringer (here Lupin) must prove by clear and convincing evidence that the patent is invalid or unenforceable. *Microsoft Corp. v. i4i Ltd. Partnership*, 131 S. Ct. 2238, 2242 (2011). To defeat Plaintiffs' injunction based on invalidity, Lupin "must establish a substantial question

of invalidity or unenforceability, *i.e., that it is likely to succeed in proving invalidity or unenforceability of the asserted patents*." *See Abbott Labs. v. Andrx Pharms., Inc.*, 473 F.3d 1196, 1201 (Fed. Cir. 2007) (emphasis added).[6]

As detailed below, Lupin's [REDACTED] non-infringement argument is directly contrary to the FDA-approved label for its generic product, and relies on irrelevant and scientifically unreliable data. Likewise, Lupin's invalidity challenge lacks merit and simply recites prior art references previously considered by the Patent Office. Therefore, Plaintiffs are likely to succeed on the merits of their claims of patent infringement.

2. Plaintiffs Are Likely To Prove Patent Infringement by Lupin

To enjoin Lupin from further distribution of its generic version of FORTAMET, Plaintiffs need only prove a likelihood that Lupin infringes *one* of the asserted claims of the '866 patent (claims 1, 3-5, and 25). *Abbott Labs.*, 473 F.3d at 1201. "Literal infringement of a claim exists when every limitation recited in the claim is found in the accused device." *Cole v. Kimberly-Clark Corp.*, 102 F.3d 524, 532 (Fed. Cir. 1996), *cert. denied*, 522 U.S. 812 (1997). A claim limitation is present if it exists in the accused product as it is described in the claim language. *See Markman* v. *Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc). Here, Lupin's generic copy of FORTAMET literally infringes each of these claims of the '866 patent.

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[6] There is a debate within the Federal Circuit, which has appellate jurisdiction over patent cases, as to whether an alleged infringer can defeat a motion for an injunction by showing a "substantial question of invalidity" of a patent if it does not also establish a likelihood of success at trial, with recognition of the presumptions and burdens, *i.e.*, the presumption of validity and the burden to prove invalidity by clear and convincing evidence. *See e.g., Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1363-74 (Fed. Cir. 2008); *Kimberly-Clark Worldwide, Inc. v. First Quality Baby Products, LLC*, -- F.3d --, 2011 WL 4495619 (Fed. Cir. Sept. 29, 2011) (Newman, J., dissenting from denial of the petition for rehearing en banc) (nonprecedential). Shionogi agrees with Judge Newman's analysis that the correct standard is likelihood of success at trial "upon application of the standards of proof that will prevail at trial" - not a lesser standard. *Id.* at 1364. The Federal Circuit's debate, however, does not affect the outcome here because Lupin's challenges to the '866 patent's validity lack merit under either standard.

As set forth in detail in the Declaration of Dr. Robert O. Williams, PhD, Lupin's generic product meets every limitation recited in claims 1, 3-5 and 25 of the '866 patent. (Williams Decl. at ¶¶11-54.) **REDACTED**

REDACTED

Lupin does not dispute (and in fact concedes) that its generic product contains *all but one* of these claim limitations. Indeed, Lupin has consistently argued in this case that its generic product does not infringe the '866 patent *for a single reason.* In Lupin's December 3, 2008 Paragraph IV certification, which required a "detailed statement" of the factual and legal bases for Lupin's opinion that it will not infringe '866 patent, *see* 21 U.S.C. § 355(j)(2)(B)(iv)(II),

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(Noyes Decl., Ex. 5 at p. 18.) Lupin did not identify or "detail" any other limitations of the '866 patent that, in its opinion, are allegedly missing from its generic copy of FORTAMET. (*Id.*) Lupin's failure to do so is an admission that its generic product meets all **REDACTED**

[7] During claim construction, Lupin argued that its generic product did not infringe because it did not have the claimed "passageway" under Lupin's proposed construction for that term. However, this Court rejected Lupin's proposed definition of passageway

[8] **REDACTED**

of claims 1, 3-5 and 25 of the '866 patent.

Lupin's September 14, 2010 Non-Infringement Contentions further confirmed that Lupin's sole non-infringement argument is the alleged absence of **REDACTED** in its generic product. (Noyes Decl., Ex. 9.) Lupin's contentions, provided pursuant to N.J. Patent L.R. 3.6(d), were required to "specifically identify for each claim which claim limitation(s) is/(are) literally absent from [Lupin's] allegedly infringing Abbreviated New Drug Application."

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REDACTED (*Id.* at 42). Given the explicit requirements of the local rules, and the nearly two years that passed between service of Lupin's Paragraph IV Certification and its contentions, Lupin's failure to identify *any* other limitations allegedly absent in its generic product is strong evidence that its generic copy of FORTAMET meets every other limitation of the claims.[9]

Lupin's sole non-infringement argument—**REDACTED**

REDACTED

REDACTED (Noyes Decl., Ex. 2.) In a section entitled "Pharmacokinetics and Drug Metabolism," Lupin's approved label states that metformin extended-release tablets have a mean T_{max} of 6 hours when administered after dinner. (*Id.* at 2; Declaration of Lawrence J. Fleckenstein, Pharm.D. ("Fleckenstein Decl. ¶53).) Lupin's approved label presents those results in the table

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9 In the year since submitting its Non-Infringement Contentions in September 2010, Lupin has not sought leave to amend to add additional non-infringement arguments. *See* N.J. Pat. R. 3.7 ("Amendment of any contentions, disclosures, or other documents required to be filed or exchanged pursuant to these Local Patent Rules may be made only by order of the Court upon a timely application and showing of good cause.")

10 The proposed label for a generic drug "must be the same as the labeling approved for the reference listed drug[.]" 21 C.F.R. § 314.94(a)(8)(iv); *Abraxis Bioscience, Inc. v. Navinta LLC*, 2008 U.S. Dist. LEXIS 63598, at *10 n.1 (D.N.J. July 31, 2008), *vacated on other grounds*, 625 F.3d 1359 (Fed. Cir. 2010).

reproduced below:

REDACTED

(*Id.*, Ex. 2 at 2; Noyes Decl., Ex. 2.) In addition, Lupin's label states, "[w]hen metformin hydrochloride extended-release tablets was administered with food… T_{max} was more prolonged compared with the fasting state (*6.1 versus 4.0 hours*)." (*Id.* (emphasis added)).

Given that Lupin's FDA-approved label explicitly identifies a mean Tmax within the range claimed by the '866 patent (*i.e.,* 5.5 to 7.5 hours for claims 1 and 25, and 5.5 to 7.0 hours for claim 3), Lupin's REDACTED non-infringement argument necessarily must fail. Lupin's "proposed label must be truthful and accurate; the proposed label is submitted to the FDA under penalty of perjury." *Research Foundation of State University of New York v. Mylan. Pharms. Inc.*, 723 F. Supp. 2d 638, 647 (D. Del. 2010) (holding that generic's label provided "substantial evidence" of infringement). If Lupin's generic copy of FORTAMET does not, in fact, have a mean T_{max} within the claimed range, **REDACTED** then Lupin's approved label is neither truthful nor accurate. The Court thus need look no further than Lupin's own product label to determine that Plaintiffs are likely to succeed in their infringement contentions against Lupin.

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In addition, by filing its ANDA, Lupin necessarily represented to the FDA that its generic copy of FORTAMET is bioequivalent to, and has the same active ingredient, route of administration, dosage form, and strengths as branded FORTAMET—representations that are necessary to obtain FDA approval for a generic drug. 21 U.S.C. §355(j)(2)(A). In claiming

REDACTED

bioequivalence, Lupin necessarily represented to the FDA that the extent and rate of absorption of its generic drug (which includes T_{max}) are not significantly different from that of FORTAMET. *See* 21 U.S.C. § 355(j)(8)(B)(i); *see also Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1244, n.2 (Fed. Cir. 2000) (same).[15]

REDACTED

Because Lupin has claimed that its generic copy of FORTAMET is bioequivalent to an embodiment of the '866 patent, and that generic was approved by the FDA based, at least in part, on claims of bioequivalence, it necessarily follows that Lupin's generic product falls within the scope of the asserted claims of the '866 patent– and thus infringes the patent.

For these reasons, Shionogi has met its burden of showing a reasonable likelihood of success on its claim that Lupin infringes the '866 patent.

3. Lupin Cannot Satisfy Its Burden of Proving Invalidity

With infringement established, Shionogi need only show that the '866 patent is reasonably likely to withstand Lupin's invalidity challenge. Lupin faces a burden of proving invalidity by clear and convincing evidence – a high and exacting standard. *See Microsoft Corp. v. i4i Ltd. Partnership*, 131 S. Ct. 2238, 2242 (2011); *Nystrom v. TREX Co. Inc.*, 424 F.3d 1136, 1149 (Fed. Cir. 2005). Lupin can make no such showing.

Because it has already been examined by the Patent Office, a patent is presumed valid at every stage of litigation, including preliminary injunction proceedings. *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1375 (Fed. Cir. 2006) (patents "presumed valid, and this

[15] Alternatively, a drug is bioequivalent to a listed drug if the extent of absorption is not significantly different from that of the listed drug and the drug's rate of absorption differs from that of the listed drug and the difference in the rate of absorption is intentional, is reflected in the labeling of the product, and is medically insignificant for the drug. *See* 21 U.S.C. § 355(j)(8)(B)(ii); 21 C.F.R. § 320.1(e). No such difference is reflected in Lupin's label.

presumption exists at every stage of the litigation") (quoting *Canon Computer Sys., Inc. v. Nu-Kote Int'l, Inc.*, 134 F.3d 1085, 1088 (Fed. Cir. 1998)). In a request for a preliminary injunction, the "burden of establishing invalidity remains on the challenger." *H.H. Robertson, Co. v. United Steel Deck, Inc.*, 820 F.2d 384, 387 (Fed. Cir. 1987) (citing *Roper Corp. v. Litton Sys.*, 757 F.2d 1266, 1270 (Fed. Cir. 1985)), *abrogated on other grounds by Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995) (en banc).

Thus, "if [Lupin] fails to identify any persuasive evidence of invalidity, the very existence of the patent satisfies [Plaintiffs'] burden on validity." *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1365 (Fed. Cir. 2001).

The burden of meeting the threshold for invalidity – clear and convincing evidence – is particularly heavy where, as here, the primary prior art Lupin cites was either already considered by the Patent Office during prosecution, or merely cumulative of the considered art. *See, e.g., PharmStem Therapeutics v. Viacell, Inc.*, 491 F.3d 1342, 1366 (Fed. Cir. 2007) ("When the party asserting invalidity relies on references that were considered during examination or reexamination, that party bears the added burden of overcoming the deference that is due to a qualified government agency presumed to have done its job.") (quotation marks omitted); *Impax Labs., Inc. v. Aventis Pharms., Inc.*, 468 F.3d 1366, 1378 (Fed. Cir. 2006) ("When the prior art was before the examiner during prosecution of the application, there is a particularly heavy burden in establishing invalidity.").

a. The Patent Office Issued the '866 Patent Over Lupin's Asserted Prior Art

On September 14, 2010, Lupin served invalidity contentions alleging that the '866 patent was both anticipated and obvious. (Noyes Decl., Ex. 10.) Although Lupin identified a laundry list of references in its contentions, it relies primarily on prior art specifically considered by the

Patent Office during prosecution. In fact, Lupin's contentions mirror the preliminary positions taken by the Patent Office during prosecution of the '866 patent. (Williams Decl. at ¶¶62-67.). However, the patentees overcame these references and arguments during prosecution. (*Id.*) As a result, Lupin has an "added burden" because the determination of the expert examiners at the PTO is entitled to deference. *See PharmStem*, 491 F.3d at 1366. Lupin does not and cannot meet its heavy burden.

In particular, Lupin argues that the '866 patent claims are invalid as anticipated by a published patent application, WO 99/47128, by Timmons. Lupin further argues that the patent claims are invalid as obvious in view of Timmons, either alone or in combination with a second published patent application, WO 99/47125, by Cheng et al. (Noyes Decl., Ex. 10.) Both of these references, however, *are expressly disclosed in the specification of the '866 patent.* Timmons is discussed in the "Background of the Invention" (*see* id., Ex. 4, '866 patent at 2:34-45), and Cheng, which shares all of the same inventors as the '866 patent, is described as "[o]ur own WO 99/47125 disclos[ing] controlled release metformin formulations providing a Tmax from 8 to 12 hours." (*Id.*, '866 patent at 2:46-47. The Patent Office issued the '866 patent after fully considering these references. (Williams Decl. at ¶62-67.)

To the extent Lupin has identified prior art references that were not before the Patent Office during prosecution, they are equally unavailing. (Williams Decl. at ¶68.) The allegedly "new" references on which Lupin relies are, in fact, nothing more than articles directed to general concepts relating to metformin, the study of gluconeogenesis, or tests of controlled-release metformin formulations that fail to teach the limitations of the asserted claims of the '866 patent. (*Id.* at ¶¶69-71.) In sum, the additional references Lupin cites in its invalidity contentions are either irrelevant or cumulative of the approximately fifty prior art references considered by

the Patent Office before allowing the '866 patent. (*Id.* at ¶72.) Lupin's decision to simply rehash arguments already raised, considered, and overcome during prosecution, and to further cite a litany of either immaterial or cumulative references simply cannot satisfy Lupin's heavy burden of demonstrating invalidity by clear and convincing evidence. *See Sanofi*, 470 F.3d at 1375-78 (declining to find anticipation of the patent-in-suit where the prior art was before the examiner during prosecution).[16]

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Shionogi's ability to succeed on the merits of its infringement claim is strong evidence that it will be irreparably harmed. *See Bosch v. Pylon Mfg. Corp.*, No. 2011-1096, slip. op. at 10-11 (Fed. Cir. October 12, 2011). Lupin cannot overcome this evidence of harm. When a generic company like Lupin **REDACTED** with infringing product, the harm to the branded company is swift and irreversible, and monetary damages are insufficient to compensate for that harm. Indeed, courts have recognized that an "at risk" launch results in "rapid loss of market share and revenue that will be difficult, if not impossible for [the branded drug] to recover..." *Eli Lilly and Co. v. Teva Pharms USA, Inc.*, 609 F. Supp. 2d 786, 811 (S.D. Ind. 2009).[17] When an infringing launch has already occurred, as it has here, the harm caused by the generic is so significant that it justifies a recall of the generic drug. "[U]nless a recall is Ordered, given the

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[16] Lupin has not and cannot make a prima facie case of non-obviousness. However, even if it could, objective indicia of non-obviousness, including long-felt need, failure of others, unexpected results, praise by industry, commercial success, and copying would demonstrate the validity of '866 patent. *See Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1380 (Fed. Cir. 2006). Such objective indicia are often the most probative evidence of non-obviousness. *Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1579 (Fed. Cir. 1997). In particular, the fact that Lupin and Mylan have sought to enter the metformin market by copying FORTAMET, rather than copying the design of other available metformin formulations (such as generic metformin), is strong evidence supporting non-obviousness.

[17] Shionogi's showing of irreparable injury in this case is even more compelling than in *Lilly*. Lilly's EVISTA® generated approximately $1 billion in annual sales, and the company had about $20.3 billion in annual sales. By contrast, in 2010, FORTAMET represented **REDACTED** Shionogi's total profits. (Melloy Decl. at ¶14.)

possibility that substantial amounts of generic product have entered the marketplace, preliminary injunctive relief would be inadequate and ineffective in ameliorating the harm ...." *Ortho McNeil*, 2009 WL 2182665 at *11 (D.N.J. July 22, 2009); *see also In re Cyclobenzaprine (Mylan)*, Civ. No. 09-MD-2118-SLR, 2011 U.S. Dist. LEXIS 54062 at *9 (D. Del. May 20, 2011) ("[P]laintiffs could recover some of their monopoly pricing if the court were to order a restraining order and plaintiffs took their authorized generic off of the market.")

REDACTED In analyzing irreparable harm, courts look to factors such as lost market share, lost business opportunities, loss of workforce, and loss of funding for research and development. *See Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1361-62 (Fed. Cir. 2008) (evidence of loss of revenue and market share supported a finding of irreparable harm); *Sanofi-Synthelabo*, 470 F.3d at 1381-83 (evidence of potential layoffs and discontinuance of clinical trials supported finding of irreparable harm); *Polymer Technologies v. Bridwell*, 103 F.3d 970, 975-76 (Fed. Cir. 1996) (decline in market share can constitute irreparable harm). **REDACTED**

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1. Loss of Revenue, Market Share and Jobs

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It is well-established that generic entrants rapidly gain significant market share, even in the short run, at the expense of the branded product. (*Id.* at ¶30; *see also id.* at ¶¶30-40, 43.). This phenomenon is driven largely by mandatory generic substitution laws in almost every state requiring substitution of the generic for the branded product. (*Id.* at ¶29.) Losses can reach up to

90 percent of prescription volume in a short amount of time, depending on various marketplace characteristics relating to the particular drugs. (*Id.* at ¶43.) For example, in *Lilly*, the court found that Teva's proposed generic would capture 80% of the Evista® market within two months of launch. *Lilly*, 609 F. Supp. 2d at 811, nn. 22, 23. The court also noted that Pravacol® and Zoloft® had lost approximately 80% of their prescriptions to generics within three weeks of entry. *Id.*; *see also Ortho McNeil*, 2009 WL 2182665 (D.N.J. July 22, 2009) (plaintiff demonstrated irreparable harm where expert estimated that, based on historical comparisons, entry of generic would cause 80% drop in net sales within 12 months).

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REDACTED will extend well beyond the date when Lupin is compelled to withdraw from the marketplace. (Vellturo Decl. at ¶¶46-67 (describing, *inter alia*, loss of market share, formulary position, goodwill, and capacity to bring new products to market).) Generic manufacturers who launch their generic products at-risk have the incentive to "flood the market" by supplying many months of the generic product upon launch. (*Id.* at ¶46.) This behavior has been observed in past instances of at-risk generic launches. For example, during its three week at-risk launch of a generic competitor to Plavix® in August 2006, Apotex placed so much of its product in the market that nine months later, in March 2007, Apotex's generic product still represented **REDACTED**

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Lupin's launch of its generic copy of FORTAMET follows this pattern. REDACTED s

REDACTED

shipments by Lupin before a decision following trial REDACTED

REDACTED

REDACTED

REDACTED cannot be remedied by money damages alone. If Lupin's generic copy of FORTAMET is allowed to remain on the market, REDACTED

REDACTED (Melloy Decl. at ¶30.) REDACTED

REDACTED (*Id.*) *See also Sanofi-Synthelabo*, 470 F.3d at 1382-83 (affirming district court's finding of irreparable harm based on, *inter alia,* REDACTED

Shionogi's market research efforts in the United States for products in the development

REDACTED

REDACTED (Melloy Decl. at ¶30.) This will result in a REDACTED for the eventual U.S. launch of Shionogi's pipeline products, REDACTED

REDACTED

2. Loss of Formulary Status

REDACTED

Unless the Lupin generic product is removed from the market, REDACTED

REDACTED

3. Entry of an Authorized Generic

REDACTED

REDACTED Lupin's launch has now created the opportunity REDACTED

REDACTED

REDACTED

4. Loss of Goodwill

REDACTED

REDACTED *See Sanofi-Synthelabo*, 488 F. Supp. 2d at 342-44 (finding irreparable harm based on price erosion and damage to consumer goodwill in support of grant of preliminary injunction in ANDA context). REDACTED

REDACTED

REDACTED

REDACTED Studies in economics and marketing suggest that Shionogi could experience a loss of goodwill because patients would become accustomed to purchasing Lupin's lower priced generic product and would have to switch to the more expensive brand (*i.e.*, patients would incur higher copays). (*Id.*)

Finally, a loss of reputation and quality control could negatively affect Shionogi's market positioning as an innovative branded drug producer and would restrict its strategic options in the

face of future competitive challenges. (*Id.* at ¶67.) REDACTED

REDACTED

Simply stated, there is no adequate remedy at law for the harm that would be inflicted on Shionogi, REDACTED and the benefits to the public in the development of new drugs. *See Lilly*, 609 F. Supp. 2d at 811-12 ("[E]ven if, as Teva contends, Lilly were able to fully recover its position in the market, we find that there would nonetheless likely be irreparable damage to Lilly's relationship with physicians and customers in addition to causing a significant disruption or loss of research that otherwise would have been sponsored or completed by Lilly as well as a scaling back of investment in research and development which otherwise would not have occurred."). Only an Order preventing Lupin from making additional infringing sales, and recalling infringing product in the market, can protect Shionogi from further irreparable injury.

D. The Balance of Hardships Strongly Favors Injunctive Relief

In stark contrast to REDACTED that continued sales of Lupin's infringing product will have on Shionogi, the injunctive relief sought here would have little or no adverse effect on Lupin. Lupin has only recently entered the market—and at its own risk while this patent infringement suit was pending. Any harm to Lupin is entitled to little weight because it is "the result of its own calculated risk to launch its product prejudgment." *Sanofi-Synthelabo*, 470 F.3d at 1383; Ortho *McNeil*, 2009 WL 2182665, at *11 ("this hardship is solely of Barr's own making"). REDACTED

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However, an injunction would not cause significant hardship for Lupin. At most, it

would experience a delay in anticipated future revenue. *See In re Cyclobenzaprine (Mylan)*, 2011 U.S. Dist. LEXIS, at *10 ("[T]here will always be a public that is willing to purchase a generic version of a branded drug."). In comparable circumstances, numerous courts have concluded that the effects of generic entry on a branded drug's existing market share greatly outweighs the effects of injunctive relief on the generic drug's future market share. *See, e.g.*, *Albany Molecular v. Dr. Reddy's*, No. 09-4638, 2010 U.S. Dist. LEXIS 59236, at *32 (D.N.J. June 14, 2010) ("Any sales that [generic seller] would lose if this injunction is improvidently granted would be time-shifted, and lost sales will not be destroyed. [The branded seller], on the other hand, would suffer devastating and irreversible losses if an injunction is not issued[.]"); *Ortho McNeil Pharm.*, 2009 WL 2182665, at *11 ("[T]he hardship to Ortho from allowing a generic competitor into the marketplace far outweighs any hardship to Barr."). "Simply put, an alleged infringer's loss of market share and customer relationships, without more, does not rise to the level necessary to overcome the loss of exclusivity experienced by a patent owner due to infringing conduct." *Pfizer, Inc. v. Teva Pharms., USA, Inc.*, 429 F.3d 1364, 1382 (Fed. Cir. 2005).

E. The Public Interest Favors Injunctive Relief

Finally, granting injunctive relief in this case will serve the strong public interest in enforcing patent rights and encouraging innovation. *See Abbott Labs*, 544 F.3d at 1363 ("'The patent laws promote this progress by offering a right of exclusion for a limited period as an incentive to inventors to risk the often enormous costs in terms of time, research, and development.'" (quoting *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974)); *Sanofi-Synthelabo*, 470 F.3d at 1383-84 (same). The public interest analysis "includes consideration of whether, by shifting market benefits to the infringer while litigation is pending for patents that are likely to withstand the attack, the incentive for discovery and development of new products is

adversely affected." *Abbott Labs.*, 544 F.3d at 1362. Permitting continued sales of Lupin's infringing products would shift the lawful economic benefits of Shionogi's licensed patents to Lupin, a precedent that would adversely affect drug developers' incentives to take risks in pursuit of new products that benefit the public.

The public interest in obtaining lower-priced generic alternatives to brand name prescription drugs does not overcome these considerations. *See Pfizer,* 429 F.3d at 1382 ("Selling a lower priced product does not justify infringing a patent." (internal quotation marks omitted)). Nor does the Hatch-Waxman Act alter the balance of public interests. *See id.* ("[W]hile the statutory framework under which Ranbaxy filed its ANDA does seek to make low cost generic drugs available to the public, it does not do so by entirely eliminating the exclusionary rights conveyed by pharmaceutical patents."). Moreover, courts confronted with the circumstances of this case have repeatedly held that the public interest in encouraging and incentivizing pharmaceutical R&D outweighs the public's interest in expedited access to generic drugs. *See Sanofi-Synthelabo*, 470 F.3d at 1383-85 (affirming district court's finding that "the interest in encouraging and incentivizing pharmaceutical research and development" outweighed the public interests advanced by the generic drug manufacturer); *Hoffmann-La Roche Inc. v. Cobalt Pharms. Inc.*, No. 07-4539, 2010 WL 4687839, at *13 (D.N.J. Nov. 10, 2010) (holding that public interest in "encouraging investment in drug development" outweighed interest in "availability of low cost drugs"); *Research Found. of State Univ. of N.Y. v. Mylan Pharms., Inc.*, 723 F. Supp. 2d 638, 663 (D. Del. 2010) ("[T]he public interest in ... investment in research and development of new pharmaceuticals[] outweighs the public's interest in promoting generic, low-cost alternatives to branded pharmaceuticals."); *Abbott Labs. v. Sandoz, Inc.*, 500 F. Supp. 2d 807, 846 (N.D. Ill. 2007) ("To the extent that this Court has found a substantial likelihood that

the '718 patent is valid and enforceable, there can be no serious argument that public interest is not best served by enforcing it."), *aff'd,* 544 F.3d 1341 (Fed. Cir. 2008).

Granting injunctive relief will additionally serve the public interest in judicial efficiency. If Lupin is allowed to market its admittedly infringing drug formulation now, a later decision by the Court decision that the '866 patent is infringed and not invalid will require the parties and the Court to engage in the extremely difficult task of quantifying the total injury to Shionogi caused by Lupin's infringing conduct. Granting of injunctive relief now will conserve judicial resources.

F. Recall of Lupin's Generic Is Necessary to Enforce the Injunction

A court order requiring Lupin to refrain from additional sales solves only a portion of the harm inflicted upon Shionogi by Lupin's actions. Drugs may leave a manufacturer's hands and travel through a distribution channel – often including both distributors and then retailers – substantially before they reach the patients' hands.

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REDACTED But there can be little doubt that, even if Lupin stops shipping new product, residual products could remain for some time in distribution channels to be sold to customers in contravention of Plaintiffs' exclusive patent rights. Courts have ordered recalls of generic pharmaceutical products in similar situations. *See, e.g., Ortho McNeil Pharm.,* 2009 WL 2182665 (court ordered recall of Barr TCL products placed into stream of commerce and immediate retraction of sales offers); *Abbott Labs. v. Sandoz, Inc.*, 500 F. Supp. 2d 807, 833, 846 (N.D. Ill. 2007) (court ordered recall of generic extended-release Biaxin even though two other generic competitors would be able to enter the market pursuant to settlement agreements), *aff'd*, 544 F.3d 1341 (Fed. Cir. 2008).

Thus, any injunctive relief should include a recall component.[18] Lupin should not, in equity, be allowed to **REDACTED** with infringing product and then to argue that such a large inventory is too expensive or difficult to recall.

V. CONCLUSION

For the reasons set forth above, the Court should grant Shionogi's motion, enter a preliminary injunction against Lupin, and order a recall of Lupin's generic copy of FORTAMET currently in the market.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Karen Jacobs Louden

Jack B. Blumenfeld (#1014)
Karen Jacobs Louden (#2881)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@mnat.com
klouden@mnat.com

Attorneys for Plaintiff Shionogi

OF COUNSEL:

Christopher R. Noyes
WILMER CUTLER PICKERING HALE AND DORR LLP
60 State Street
Boston, MA 02109
(617) 626-6000

David A. Manspeizer
David B. Bassett
Peter Shen
WILMER CUTLER PICKERING HALE AND DORR LLP
399 Park Avenue
New York, NY 10022
(212) 230-8800

Liza M. Walsh
Rukhsanah Lighari
CONNELL FOLEY LLP
85 Livingston Avenue
Roseland, NJ 07068
(201) 521-1000

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[18] At the very least, Lupin should be required to notify all of their distributors and/or retailers of any injunctive relief granted by the Court.

CERTIFICATE OF SERVICE

I hereby certify that on October 19, 2011, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following:

Richard D. Kirk, Esquire
Stephen B. Brauerman, Esquire
BAYARD, P.A.

Richard Herrmann, Esquire
Mary B. Matterer, Esquire
MORRIS JAMES LLP

Frederick L. Cottrell, III, Esquire
Steven J. Fineman, Esquire
RICHARDS, LAYTON & FINGER P.A.

I also certify that copies were caused to be served on October 19, 2011 upon the following in the manner indicated:

Richard D. Kirk, Esquire — *VIA ELECTRONIC MAIL*
Stephen B. Brauerman, Esquire
BAYARD, P.A.
222 Delaware Avenue – Suite 900
Wilmington, DE 19801
Attorneys for Lupin Ltd. and Lupin Pharmaceuticals, Inc.

Douglass C. Hochstetler, Esquire — *VIA ELECTRONIC MAIL*
Jason G. Harp, Esquire
Kathryn S. Devine, Esquire
SCHIFF HARDIN LLP
6600 Sears Tower
Chicago, IL 60606
Attorneys for Lupin Ltd. and Lupin Pharmaceuticals, Inc.

Beth D. Jacob, Esquire — *VIA ELECTRONIC MAIL*
SCHIFF HARDIN LLP
666 Fifth Avenue
New York, NY 10103
Attorneys for Lupin Ltd. and Lupin Pharmaceuticals, Inc.

Karen A. Confoy, Esquire — *VIA ELECTRONIC MAIL*
Erica A. Helms, Esquire
STERNS & WEINROTH PC
50 West State Street
Suite 1400
Trenton, NJ 08607
Attorneys for Lupin Ltd. and Lupin Pharmaceuticals, Inc.

Richard Herrmann, Esquire — *VIA ELECTRONIC MAIL*
Mary B. Matterer, Esquire
MORRIS JAMES LLP
500 Delaware Avenue – Suite 1500
Wilmington, DE 19801
Attorneys for Mylan Inc. and Mylan Pharmaceuticals Inc.

Timothy H. Kratz, Esquire — *VIA ELECTRONIC MAIL*
Robert L. Florence, Esquire
George J. Barry III, Esquire
MCGUIRE WOODS LLP
1230 Peachtree Street, N.E.
Suite 2100
Atlanta, GA 30309
Attorneys for Mylan Inc. and Mylan Pharmaceuticals Inc.

Frederick L. Cottrell, III, Esquire — *VIA ELECTRONIC MAIL*
Steven J. Fineman, Esquire
RICHARDS, LAYTON & FINGER P.A.
One Rodney Square
Wilmington. DE 19801
Attorneys for Andrx Corporation, Andrx Pharmaceuticals, Inc. (n/k/a Watson Laboratories, Inc.-florida), Andrx Pharmaceuticals, L.L.C., Andrx Laboratories (NJ), Inc., Andrx EU Ltd. and Andrx Labs, L.L.C.

Gary E. Hood, Esquire *VIA ELECTRONIC MAIL*
POLSINELLI SHUGHART PC
161 North Clark Street – Suite 4200
Chicago, IL 60601-3316
Attorneys for Andrx Corporation, Andrx Pharmaceuticals, Inc. (n/k/a Watson Laboratories, Inc.-florida), Andrx Pharmaceuticals, L.L.C., Andrx Laboratories (NJ), Inc., Andrx EU Ltd. and Andrx Labs, L.L.C.

Robyn H. Ast, Esquire *VIA ELECTRONIC MAIL*
POLSINELLI SHUGHART PC
100 South Fourth Street
Suite 1000
St. Louis, MO 63102
Attorneys for Andrx Corporation, Andrx Pharmaceuticals, Inc. (n/k/a Watson Laboratories, Inc.-florida), Andrx Pharmaceuticals, L.L.C., Andrx Laboratories (NJ), Inc., Andrx EU Ltd. and Andrx Labs, L.L.C.

/s/ Karen Jacobs Louden

Karen Jacobs Louden (#2881)